## REMARKS

Claims 1 – 98, 133, 134, and 136 – 168 remain pending in the present application. However, claims 1 – 3, 5 – 7, 11 – 17, 50 – 52, 54 – 56 and 60 – 66 have been rejected, 4, 8 – 10, 18 – 49, 53, 57 – 59, 67 – 98, 133, 134, and 136 – 168 have been withdrawn pursuant to a restriction requirement and claims 99 – 132 and 135 have been previously canceled. Applicant respectfully requests reconsideration by the Examiner of the pending claims in light of the following remarks.

**Claim Rejections based on 35 USC § 103**

The Examiner has rejected claims 1 – 3, 5 – 7, 11 – 17, 50 – 52, 54 – 56, and 60 – 66 under 35 U.S.C. §103(a) as being unpatentable over Dinh et al. (U.S. Patent No. 5,510,077) in view of Greatbatch (U.S. Patent No. 4,405,311) and in further view of Keusch et al. (U.S. 5,510,077). In response, Applicant respectfully traverses the above-mentioned rejections under 35 U.S.C. §103(a) and respectfully request reconsideration by the Examiner in view of the following remarks.

As is well established, the Examiner bears the initial burden in establishing a prima facie case of obviousness when rejecting claims under 35 U.S.C. §103. In re Piasecki, 745 F.2d 1468, 223 USPQ 758 (Fed. Cir. 1985); In re Reuter, 651 F.2d 751, 210 USPQ 249 (CCPA 1981). If the Examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of non-obviousness.

To properly establish a prima facie case of obviousness, the Examiner must meet a few basic criteria to support such a rejection. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. Prior art under 35 U.S.C. §103 is the same as prior art under 35 U.S.C. §102. MPEP § 2141.01. Next, "to support the conclusion

that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. KSR International Co. v. Teleflex Inc. 550 U.S. ___, 82 U.S.P.Q.2d1385, 1386 (2007)." Thus, some articulated reason with rational underpinning to support the legal conclusion of obviousness must be provided for the Examiner to meet his or her burden. M.P.E.P. §2143.01, citing KSR Int'l, 82 U.S.P.Q.2d at 1396 quoting In re Kahn, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed . Cir. 2006. "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." KSR Int'l. 127 S. Ct. 1727, 1741. Hence, "it is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does". Id. Finally, there must be a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

With regards to the rejection of the claims 1 – 3, 5 – 7, 11 – 17, 50 – 52, 54 – 56, and 60 – 66 under 35 U.S.C. §103(a) as being unpatentable over Dinh in view of Greatbatch and Keusch, the Applicant respectfully traverses the Examiners rejection due to the premise that Dinh in view of Greatbatch and Keusch fails to disclose all of the limitations of the amended claims above. For example, neither Dinh, Greatbatch or Keusch disclose a current release drug delivery device or an electromatrix device that includes the limitations of 1) an intermediate

material, the cohesive body, having a solvent content of about 20% to 80% prior to compression; and 2) the cohesive body compressed at a pressure of about 100 psi to 100,000 psi to remove bulk biocompatible solvent and generate additional intermolecular and intramolecular forces between one or more of the protein materials, conductive materials, active agents and solvents.

As previously suggested in prior office actions, the Dinh and Greatbatch references do not disclose or suggest the claimed intermediate material, the cohesive body having a solvent content of about 20% to 80%. As previously mentioned, the cohesive body having a solvent content of about 20% to 80% prior to compression is necessary to formulate the compressed current release drug delivery devices and electromatrix products of the present invention. Without a cohesive body having the proper solvent content, thereby providing the proper proportions and positioning of protein and solvent molecules, the compression will not produce the desired drug delivery device or electromatrix material. For example, too much solvent will cause the composition to be too much like a liquid, thereby preventing the material from being cohesive, i.e. the composition will not substantially stick to itself. Alternatively, too little solvent will cause the composition to crack, shatter, break or otherwise lack cohesiveness upon efforts to form the cohesive body. Compression of a cured/crosslinked material, such as the fibrin material of Dinh, will tend to cause the composition to crack, shatter, break or otherwise lack cohesiveness because the fibrin material is already in a crosslinked/fixed state. This premise is identified in Dinh at col. 10, lines 42-46 when the reference describes the fragile nature of fibrin when attempting to apply pressure to the fibrin using an inflated balloon catheter. Dinh explains that "[b]ecause fibrin is such a fragile material, it is important to control the expansion by slow expansion to prevent the fibrin from tearing…". This statement indicates that Dinh does not include a cohesive body as found in the present claims.

Moreover, the protein molecules' ability to remain mobile in a properly solvated environment, as found in the cohesive body, and to re-organize is necessary for additional binding among the protein and solvent molecules upon compression. Generally, the proper compression of a cohesive body alters protein molecule conformation and their relative position within the cohesive body, thereby bringing the protein molecules and their binding sites closer together with each other and the solvent molecules to form additional bonds that would not be formed but for the mobile characteristics maintained by the protein in the cohesive body. These mobile characteristics are not found in crosslinked matrices, such as the fibrin material of Dinh, which is formed by crosslinking fibrinogen and thrombin. Indeed, the fibrin matrix will tear under increased compression force rather than come together to form a stronger interaction among the molecules as taught by Applicant.

Furthermore, in the present invention, the proper amount of compression at a pressure of about 100 psi to about 100,000 psi allows the conformation of the protein to alter, thereby opening additional protein binding sites for interaction with additional solvent molecules, which transforms the cohesive body into a much stronger structure. This amount of compression is not disclosed or suggested in the cited references. Moreover, Dinh teaches away from using this amount of compression. For example, Dinh indicates that "[t]he balloon can then be expanded slowly at one atmosphere increments until a pressure of about six atmospheres is achieved." See Dinh at Col. 10, lines 49-51. It is noted that six atmospheres converts to approximately 88 psi, which does not fall within the claimed range. Furthermore, such interaction through compression is not possible with a crosslinked fixed material like fibrin. Hence a compressed current release drug delivery device or an electromatrix product of the present invention could not be formed by using the teachings of Dinh, Greatbatch or Keusch.

Finally, the Examiner has not provided any convincing line of reasoning why the solvent content of the polyethylene (PEO) hydrogel of Keusch could be combined with a fibrin protein material of Dinh to meet the limitations of the present claims. It is noted that the final products, as claimed in the present application, are the result of a precise interaction between the proteins and the solvent present in the products. It is generally known in the art that such interactions between components cannot be readily assumed when taking into consideration different components (e.g. proteins v. PEO). Proteins and PEO have very different properties and interact with solvents in very different ways. Furthermore, the properties found in the products as claimed are substantially derived through the interaction between the proteins and the solvents wherein the solvent content can greatly influence the production of the final product. In view of the components of Dinh (i.e. fibrin) and Keusch (i.e. PEO) being very different, a person of ordinary skill in the art would not believe that interchanging or utilizing the solvent content of Keusch with the fibrin of Dinh would produce the invention as claimed in the present application. Therefore, no convincing line reasoning has been provided or could be provided that would lead to such a conclusion. In view of the failure to provide any convincing line of reasoning as to combining the Dinh reference and the Keusch reference, the Applicant respectfully requests that this rejection be withdrawn and that the pending claims be allowed.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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